Remarks

Claims 1-16 are pending in the application, however claims 3-4 and 14-16 are withdrawn and have not been examined. Applicant has elected an azole antifungal agent as the species for initial prosecution in response to a requirement for election of species and these claims have been examined at this time. The subspecies itraconazole also was elected. To further prosecution at this time, claim 1 has been amended to correspond to the elected species, however applicant reserves the right to continue prosecution of this subject matter in a later-filed continuation or divisional application. Claim 2 is canceled herein as redundant in light of these amendments to claim 1.

Claims 1-2, 5-7 and 9-13 are rejected as anticipated by Ponikau et al. To make out a case of anticipation over a reference, the Office must show that the reference discloses, within its four corners, each and every limitation of the rejected claim. M.P.E.P. §2131. Ponikau et al. are cited for teaching an antifungal agent to treat otitis media and rhinosinusitis, including the agent itraconazole, 100 mg/day.

The Ponikau et al. reference describes an invention based on the asserted discovery that chronic rhinosinusitis is caused by non-invasive fungal organisms and that these chronic conditions can be treated or prevented using various forms of "mucoadministration." See column 12, lines 62-63. In the summary of the invention, Ponikau et al. described several embodiments relating to the condition rhinosinusitis. Each of these methods involves "direct" mucoadministration of an antifungal agent (see column 3, line 60; column 5, line 49) with an optional additional step involving prophylactic "indirect" mucoadministration. The prophylactic step also may be performed

alone (see column 5, lines 9-12, 39-41). Therefore, Ponikau et al. teach treatment of chronic rhinosinusitis using direct mucoadministration, defined in the specification as administration that directly contacts the targeted mucus prior to crossing epithelium (column 23, lines 32-35 and 57-66) and/or prophylaxis of chronic rhinosinusitis with an oral medication.

Applicant has amended the claims to recite a method of treating acute maxillary sinusitis of fungal origin. Support for this amendment is found throughout the specification, for example paragraph 2. The method recites orally administering an azole antifungal agent for treatment of an acute maxillary sinusitis of fungal origin. The cited reference repeatedly refers to chronic conditions such as allergic fungal sinusitis and asthma, and describes direct application to the affected mucosa for its treatment methods. It does not teach or suggest any method for treating acute maxillary sinusitis or any treatment methods (as distinguished from prophylactic methods) for these conditions using oral medication for a sinus affliction, i.e. "direct" administration to use the terminology of Ponikau et al. Ponikau et al. do not even mention treatment of a sinus condition with oral medication.

Applicant therefore submits that the Ponikau et al. reference does not teach or suggest each and every claim element of the claims rejected here, including methods for treating acute maxillary sinusitis of fungal origin by orally administering an azole antifungal agent. Applicant therefore requests that the Office withdraw this rejection.

Claim 8 is rejected as obvious over the Ponikau et al. reference discussed above. The Office concedes that the reference does not teach administration of a therapeutically effective amount of antifungal agent of 200-400 mg/day. The

Office Action states that Ponikau et al. teach using about 0.01 ng to about 1000 mg per kg body weight. No specific citation to the Ponikau et al. patent is given. These amounts are disclosed in the reference at column 24, lines 60-63, but for direct mucoadministration only. See column 24, line 61. This range is not taught or even suggested for oral administration, and is extremely broad, encompassing doses from 0.7 ng to 70g for a 70 kg human. This extremely broad range, given for an entirely different route of administration does not suggest the range of claim 8 of the present application, for oral administration.

The general disclosures of Ponikau et al. have been discussed above. Applicant refers the Office to these discussions and reasserts that the Ponikau et al. reference does not teach or suggest each and every limitation of the claims here presented. The reference does not teach or suggest treatment with oral administration as claimed here, or treatment of acute maxillary sinusitis of fungal origin as claimed here, and does not suggest the claimed dose ranges for oral administration, much less these doses for treatment of the claimed condition.

Furthermore, there is no suggestion in the reference to modify the teachings with respect to chronic conditions involving either topical ("direct") application for treatment or prophylaxis of conditions optionally using oral administration, particularly at these doses, because there is no reasonable expectation that the "indirect" administration of antifungal medication would be effective in treating an acute condition as claimed. There is no hint in the cited reference that oral medication would be useful for treatment of an acute condition--Ponikau et al. stresses treatment should be by direct administration to the affected mucus, and no acute conditions are treated at all.

Therefore, Applicant submits that the Office cannot make out a prima facie case of obviousness against the claims of this application based on Ponikau et al., because this reference (1) lacks a teaching or suggestion of each and every claim element; (2) provides no motivation to modify its teachings in the absence of hindsight to achieve the claimed invention; and (3) does not provide a reasonable expectation that what is claimed here would be successful. Applicant therefore requests that the Office reconsider the claims here presented and withdraw the rejection of claim 8 on grounds of obviousness.

Applicants request favorable consideration of the amended claims and prompt allowance of the application.

RESPECTFULLY SUBMITTED,					
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